

Message Text

UNCLASSIFIED

PAGE 01 STATE 141667
ORIGIN HEW-06

INFO OCT-01 ARA-14 ISO-00 OES-07 EB-07 COME-00 /035 R

DRAFTED BY DHEW/FDA: JRWEINROTH:CCK
APPROVED BY OES/APT/BMP: JFRY
DHEW/PHS/OASH/OIH: MKEFAUVER
ARA/PAN:JBECKER (INFO)

-----172311Z 122877 /65

P 172243Z JUN 77
FM SECSTATE WASHDC
TO AMEMBASSY PANAMA PRIORITY

UNCLAS STATE 141667

E.O. 11652: N/A

TAGS: OGEN, ETRD, EIND, TBIO, PN

SUBJECT: FDA ADVISORY - DEFECTIVE LATEX ENDO-
TRACHEAL TUBES - RECALL (T-108-7)

1. FDA ADVISES OF THE FOLLOWING RECALL:

PRODUCT INVOLVED: RUSCH REINFORCED LATEX ENDOTRACHEAL TUBES
(CATALOGUE) MODEL NO. 102500, 103000, 101000, AND 106000,
RANGING IN LENGTH FROM 20-36 CM AND IN SIZE FROM 18-46 FR.
PRODUCT IS A NON-STERILE DEVICE USED FOR THE ADMINISTRATION
OF ANESTHETIC GASES OR AS AN EMERGENCY TRACHEOTOMY TUBE.

PRODUCT IDENTIFICATION: PRODUCT IS INDIVIDUALLY PACKAGED
IN TRANSPARENT PLASTIC SLEEVES LABELED IN PART "RUSCH
INCORPORATED XXX NEW YORK N.Y. XXX, WHICH CONTAIN BOTH THE
MODEL (CATALOGUE) NUMBER AND SIZE. ALL LOTS OF THE ABOVE
MODEL NUMBERS ARE INVOLVED. FIELD MODIFICATION CONSISTS
OF APPLYING A WARNING STICKER TO THE INDIVIDUAL PACKAGE
AND A LETTER NOTIFYING THE USER OF PROPER RESTERILIZATION
UNCLASSIFIED

UNCLASSIFIED

PAGE 02 STATE 141667

TECHNIQUES.

MANUFACTURER/RECALLING FIRM:

MANUFACTURER: RUSCH INC., STUTTGART, WEST GERMANY

RECALLING FIRM: RUSCH INC., 53 W. 23RD ST., N.Y., N.Y.

2. REASON FOR RECALL:

THE FIRM WAS INITIALLY ALERTED TO THE DEFECT PROBLEM VIA A COMPLAINT RECEIVED BY WILLY RUSCH, INC., STUTTGART, WEST GERMANY APPROXIMATELY 3 MONTHS AGO. THE FIRM DECIDED TO ATTACH STICKERS TO THE PRODUCT WARNING AGAINST THE DANGER OF SUBJECTING THE TUBES TO THE VACUUM CYCLE DURING RE-STERILIZATION.

THE STICKERS WERE INCLUDED WITH EACH UNIT FOR APPROXIMATELY ONE MONTH AT WHICH TIME THE FIRM WAS NOTIFIED BY THE MANUFACTURER THAT THE DEFECT WAS AN ISOLATED PROBLEM. THE WARNING STICKERS WERE THEN DISCONTINUED. IN EARLY APRIL, THE FIRM BECAME AWARE OF SIMILAR FAILURES. THE CHIEF OF ANESTHESIOLOGY OF THE JEFFERSON UNIVERSITY HOSPITAL, PHILADELPHIA, PA., NOTIFIED THE RUSCH SALESMAN THAT AN ENDOTRACHEAL BLOCKAGE WAS EXPERIENCED DURING SURGERY. THE FIRM WAS CONTACTED BY ANOTHER ANESTHESIOLOGIST AT THE PRESBYTERIAN HOSPITAL IN PITTSBURG, PA., WHO INFORMED THEM THAT THE HOSPITAL HAD SIMILAR FAILURES IN THESE TUBES DURING 2 SEPARATE OPERATIONS. THE FAILURE CONSISTED OF BLISTERS PRESENT ON THE INNER WALLS OF THE ENDOTRACHEAL TUBES, SWELLING DURING THE ADMINISTRATION OF GASEOUS ANESTHETICS, THEREBY BLOCKING THE CHANNEL OF THE TUBES. THE FIRM ALLEGED THAT THE INNER WALL TO THE MULTILAYERED LATEX TUBE MAY SEPARATE WHEN SUBJECTED TO THE VACUUM IMPOSED DURING GAS OR STEAM STERILIZING. THE FIRM MAINTAINED THAT WARNINGS AND PROPER RESTERILIZATION TECH-

UNCLASSIFIED

UNCLASSIFIED

PAGE 03 STATE 141667

NIQUES ARE LISTED IN THE FIRM'S CATALOG, HOWEVER, THEY ARE NOT INCLUDED WITH THE PRODUCT. FOLLOWING THE SERIES OF COMPLAINTS, THE FIRM CEASED ALL DISTRIBUTION OF THE PRODUCT AND HAD WARNING STICKERS, PROPER RESTERILIZING DIRECTIONS, AND NOTIFICATION LETTER PRINTED. THE WARNING STICKERS AND INSERTS WERE TO BE INCLUDED WITH ALL ORDERS SHIPPED AS OF APRIL 14. FOLLOWING A SERIES OF DISCUSSIONS, LETTERS AND CONFERENCES ON JUNE 6, 1977 THE FIRM DECIDED TO REFORMULATE THEIR LETTER NOT ONLY TO

INCLUDE A WARNING AGAINST THE USE OF PREVIOUSLY STERILIZED ENDOTRACHEAL TUBES THAT MAY HAVE A DEFECT, BUT ALSO AGAINST STERILIZING SYSTEMS THAT THEY PRECIPITATE THE DEFECTS.

THE FIRM ADDITIONALLY AGREED TO REQUEST LABEL MODIFICATION OF HOSPITAL INVENTORY TO INCLUDE THE ATTACHMENT OF A WARNING STICKER CAUTIONING ABOUT CERTAIN STERILIZING SYSTEMS WHICH EMPLOY A VACUUM CYCLE. THE FIRM MAILED

REVISED ADVISORY LETTERS ON JUNE 8, 1977.

3. POST IS REQUESTED TO CONTACT CONSIGNEE TO DETERMINE IF THEY HAVE BEEN ADVISED OF THE PROBLEM CONCERNING THE ENDOTRACHEAL TUBES. ANY QUESTIONS CONSIGNEE MAY HAVE REGARDING THIS RECALL SHOULD BE DIRECTED TO FIRM.

4. FOREIGN CONSIGNEE AS FOLLOWS:

HORACIO ICAZA CIA
FORMERLY: LA CASA DEL MED.
P O BOX 1689
PANAMA, REPUBLIC OF PANAMA VANCE

UNCLASSIFIED

NNN

Message Attributes

Automatic Decaptioning: X
Capture Date: 01-Jan-1994 12:00:00 am
Channel Indicators: n/a
Current Classification: UNCLASSIFIED
Concepts: MEDICAL FACILITIES
Control Number: n/a
Copy: SINGLE
Sent Date: 17-Jun-1977 12:00:00 am
Decaption Date: 01-Jan-1960 12:00:00 am
Decaption Note:
Disposition Action: n/a
Disposition Approved on Date:
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01-Jan-1960 12:00:00 am
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
Document Number: 1977STATE141667
Document Source: CORE
Document Unique ID: 00
Drafter: JRWEINROTH:CCK
Enclosure: n/a
Executive Order: N/A
Errors: N/A
Expiration:
Film Number: D770217-0800
Format: TEL
From: STATE
Handling Restrictions: n/a
Image Path:
ISecure: 1
Legacy Key: link1977/newtext/t19770643/aaaabmaj.tel
Line Count: 129
Litigation Code IDs:
Litigation Codes:
Litigation History:
Locator: TEXT ON-LINE, ON MICROFILM
Message ID: a777827a-c288-dd11-92da-001cc4696bcc
Office: ORIGIN HEW
Original Classification: UNCLASSIFIED
Original Handling Restrictions: n/a
Original Previous Classification: n/a
Original Previous Handling Restrictions: n/a
Page Count: 3
Previous Channel Indicators: n/a
Previous Classification: n/a
Previous Handling Restrictions: n/a
Reference: n/a
Retention: 0
Review Action: RELEASED, APPROVED
Review Content Flags:
Review Date: 23-Dec-2004 12:00:00 am
Review Event:
Review Exemptions: n/a
Review Media Identifier:
Review Release Date: n/a
Review Release Event: n/a
Review Transfer Date:
Review Withdrawn Fields: n/a
SAS ID: 2107210
Secure: OPEN
Status: NATIVE
Subject: FDA ADVISORY - DEFECTIVE LATEX ENDO- TRACHEAL TUBES - RECALL (T-108-7)
TAGS: OGEN, ETRD, EIND, TBIO, PN
To: PANAMA
Type: TE
vdkgvwkey: odb://SAS/SAS.dbo.SAS_Docs/a777827a-c288-dd11-92da-001cc4696bcc
Review Markings:
Margaret P. Grafeld
Declassified/Released
US Department of State
EO Systematic Review
22 May 2009
Markings: Margaret P. Grafeld Declassified/Released US Department of State EO Systematic Review 22 May 2009